	LETTER OF INTENT	**INVESTIGATIONAL DRUG TRIAL**
	National Cancer Institute **Division of Cancer Treatment and Diagnosis** **Cancer Therapy Evaluation Program**	

Group/Institution(s) _____

Agent(s) to be supplied by NCI _____

Other agents to be used in the protocol _____

_____

Tumor type _____
Performance status _____
Abnormal organ function permitted _____

_____

Prior therapy _____

Phase of study _____
Treatment plan _____

_____

_____

_____

_____

Rationale/hypothesis _____

_____

_____

_____

_____

Laboratory correlates _____

_____

_____

_____

_____

Endpoints/statistical considerations _____

_____

_____

_____

Estimated annual accrual _____
Proposed sample size _____
Earliest date study can begin _____

Projected accrual dates: Beginning ☐☐ / ☐☐ (month/year) Ending ☐☐ / ☐☐ (month/year)

To document accrual rate, list trials with patients who had similar tumor type/PS/prior Rx.

Trial *Accrual Rate* (number of patients/study duration)

List all active studies at your institution for which this patient population will be eligible.

Is this LOI part of a grant or cooperative agreement? ☐ Yes ☐ No Grant # _____

(Example: U01 CA 12345)

If proposed trial includes correlative studies, CTEP assumes you have funding to support them. If not, please explain:

Name of Principal Investigator (Printed) Signature Date

Phone: _____ Street Address: _____

Fax: _____

e-mail: _____

Name of Group Chair/Cooperative Agreement PI (Printed) Signature Date

Phone: _____ Street Address: _____

Fax: _____

e-mail: _____

Cooperative group LOIs must be submitted through the group operations office and must be appropriately signed. Proposal for trials that will be conducted under cooperative agreement must be signed by the principal investigator of the agreement, as well as the protocol chair.

LOIs can be submitted to LOI Coordinator, IDB, at any of the following:

USPS Mailing Address: P.O. Box 30012, Bethesda, MD 20824
Express Mailing Address: TRI, 3202 Tower Oaks Blvd., Rockville, MD 20852
Fax: (301) 230-0159 E-mail: loi@tech-res.com
Questions? Please call LOI Coordinator at (301) 231-5250.